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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,500	06/09/2006	Sabine Hitzel	MERCK-2823	2891
23599 7590 07/09/2008 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201				
EXAMINER				
BROWN, COURTNEY A				
ART UNIT		PAPER NUMBER		
1616				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/582,500

Applicant(s)

HITZEL ET AL.

Examiner

COURTNEY BROWN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/86)
Paper No(s)/Mail Date 6/09/2006
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Receipt of Amendments/Remarks filed on February 28, 2008 is acknowledged. In response to the Restriction Requirement filed January 28, 2008, Applicant elected Group I, claims 5-8, with traverse. Applicant's Arguments, see pages 5 and 6, filed February 28, 2008, with respect to the aforementioned Restriction Requirement have been fully considered and are persuasive. The Restriction Requirement filed January 28, 2008 has been withdrawn. Claims 17-24 were added. Claims 1-24 are being examined for patentability.

Priority

Priority to Provisional Application 60/528,472 filed on December 11, 2003 is acknowledged.

Information Disclosure Statement

The Information Disclosure Statement (IDS) submitted on June 9, 2006 has been considered by the examiner.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When new claims are presented, they must be numbered consecutively beginning with the

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number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 23 (last claim in listing of claims) must be renumbered as claim 24. For examination purposes, this claim will be referred to as claim 23b.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,9,11,12, and 13 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-10 and 12 of copending Application No. 11/997,629 in view of Laughlin (US Application 2003/0019504 A1). Although the conflicting claims are not identical, they are not

patentably distinct from each other because the instantly claimed subject matter embraces or is embraced by the co-pending application.

The copending application recites the same method of self tanning the human body using a composition comprising dihydroxyacetone, glycerol, and/or propylene glycol, and uv-filters. The difference between the method of the instant invention and that of copending Application No. 11/997,629 is that instant invention requires application of the self tanning composition at elevated temperatures (i.e. 25-60 degrees Celsius). Laughlin teaches application of self tanning composition at 80-110 degrees Fahrenheit (i.e., 26.6-43.3 degrees Celsius). From this extensive overlap of subject matter, one of ordinary skill in the art would recognize that the same product is taught in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 20-24, and 26 of copending Application No. 10/930,778. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed subject matter embraces or is embraced by the co-pending application.

Copending claims 1, 20-24-34 recite the same cosmetic composition and method for coloring the skin comprising dihydroxyacetone, glycerol, and/or propylene glycol, and uv-filters. The only difference is that an esterified dihydroxyacetone derivative is used in copending Application No. 10/930,778 . It would be obvious to one of ordinary

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skill in the art to use a derivative of dihydroxyacetone because compounds that are similar in chemical structure possess the same biological properties and therefore lead to identical desired results. From this extensive overlap of subject matter, one of ordinary skill in the art would recognize that the same product is produced in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-23b are rejected under 35 U.S.C. 103 (a) as being unpatentable over Laughlin (US 20030019504 A1) in view of Ziegler et al., (US 5,232,688) and further in view of Sottery et al. (US 5,229,104).

Applicant's Invention

Applicant claims a method of self tanning comprising applying at least one self-tanning substance or a formulation that is dissolved in water and applied to the human skin using a shower, spray, bathtub, or whirlpool for whole or partial immersion, at an elevated temperature between 25-60 °C. Applicant claims the aforementioned method

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wherein a water-repellant preparation is applied to parts of the body which are not to be tanned or tanned slightly. Additionally, Applicant claims a cosmetic formulation that is a bath additive, salt, and/or a capsule comprising: a.) 0.1-10% of a fatty carrier chosen from ceramides, cholesterol, phospholipids, cholesteryl sulphate, cholesteryl phosphate, phosphatidylcholine, lecithin and/or empty liposomes; b.) one or more UV filter; c.) 0.5-20% glycerol and/or propylene glycol; and d.) .01-10% 1,3-dihydroxyacetone (i.e., dihydroxyacetone).

***Determination of the scope and the content of the prior art
(MPEP 2141.01)***

Laughlin teaches a system for coating human skin using a chemical composition that is uniformly coated over the entire body or selected parts of the body of the person being coated (abstract, claims 6,7, and 19 of instant application).

Laughlin teaches utilizing a unitary construction including both a coating chamber and apparatus for coating a person situated within the coating chamber wherein a door provides ingress to and egress from the coating chamber which is provided with vertically disposed arrays of spray discharging nozzles situated at spaced apart points around the periphery of the chamber ([0066, claim 2 of instant application, bathtub and/or whirlpool of instant application).

Laughlin teaches, by way of example, a more detailed description of functional compositions based on artificial tanning compositions comprising 3-15%

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dihydroxyacetone ([0119] and [0225], claim 14 of instant application). Laughlin also teaches dilution of the aforementioned compositions ([0130], claim 5 of instant application).

Laughlin teaches the use of numerous other colorants including erthrulose, lawsone and juglone ([0133], [0140], and [0145], claims 5 and 23 of instant application). Laughlin teaches the use of other potential additives including sunscreens ([0157], claim 1 and 11, UV filter of instant application).

Laughlin teaches atomization of the self tanning composition using misting ([0181], claim 4 of instant application).

Laughlin teaches protecting hair from the chemical sun tanning composition by coating it with a water insoluble material such as petroleum jelly. Laughlin also teaches that similar protection can be used to protect hair on any other parts of the body ([0183], claim 8, water-repellent preparation of instant application).

Additionally, Laughlin teaches application of the sun tanning composition at 26.6 to 43.3 ° C ([0255], claims 1,5, 17, and 18 of instant application).

***Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)***

The difference between the invention of the instant application and that of Laughlin is that the instant invention requires the use of specific weight percentages of the propylene glycol and 1,3- dihydroxyacetone. For these reasons, the teaching of Ziegler et al. is joined. Ziegler et al. teach a cosmetic composition comprising: (i) from about 0.1 to about 40% by weight of a C3-C24 alpha -hydroxy substituted ketone or aldehyde; (ii) from about 0.1 to about 20% by weight of a polyacrylamide; and (iii) an effective amount of a pharmaceutically acceptable vehicle for delivering components (i) and (ii) to skin. Ziegler et al. teach a method for imparting a natural-appearing, nonstreaking tan to skin comprising the delivery and spreading of the aforementioned cosmetic composition onto the skin (column 2, lines 21-33, claims 1,1315, and 20-23 of instant application). Ziegler et al. teach that the alpha-hydroxy substituted ketone or aldehyde may be selected from dihydroxacetone, glucose, xylose, fructose, reose, ribose, pentose, arabinose, allose, tallose, altrose, mannose, galactose, lactose, sucrose, erythrose , glyceraldehyde and combinations thereof with the most preferred being dihydroxacetone (column 2, lines 47-52, claims 14 and 23b of instant application). Ziegler et al. teach the use of propylene glycol at levels of at least 15% preferably between about 25 and 90%, optimally between about 25 and 45% by weight. Ziegler et al. teach that propylene glycol at these high levels improve color intensity on the skin when combined with dihydroxacetone (column 3, lines 4-13, claims 22 and 23 of instant application). Ziegler et al. teach the use of sterol esters such as cholesterol fatty esters (column 4, lines 46 and 47, claims 9 and 10 of instant application). Additionally,

Ziegler et al. teach sunscreen agents as a further desirable ingredient (column 5, lines 9-23, claims 1 and 11, UV agent of instant application).

Another difference between the invention of the instant application and that of Laughlin is that the instant invention requires to 0.1-10% of a fatty carrier chosen from ceramides, cholesterol, phospholipids, cholesteryl sulphate, cholesteryl phosphate, phosphatidylcholine, lecithin and/or empty liposomes. For this reason, the teaching of Sottery et al. is joined. Sottery et al. teach oil-in-water compositions comprising cholesterol (column 7, lines 68 to column 8, lines 1 and 2), sunscreens (abstract), dihydroxyacetone (abstract), and propylene glycol (column 4, lines 61-63).

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of the two cited references to arrive at a method and a cosmetic formulation for self tanning composition. One would have been motivated to make this combination in order to receive the expected benefit of having a method of applying a self tanning composition in a contained, relaxing environment using a cosmetic formulation that provides artificial bronzing as well as UV protection. "It would be prima facie obvious to combine two compositions and methods each of which is taught by the prior art to be useful for the same purpose in order to form a resultant composition and method that is to be used for the very same purpose; the

idea of combining them flows logically from their having been individually taught in prior art." In re Kerkhoven, 205 USPQ 1069 (C.C.P.A. 1980).

Although the aforementioned references do not teach the use of the specific weight percent of fatty acid carrier as claimed in the instant application, absent a showing of unexpected results, it would be obvious to one of ordinary skill in the art to vary the weight percentages depending on the desired result. Determining optimal weight percentages of components is routine experimentation and is readily practiced by one of ordinary skill.

Conclusion

None of the claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR Only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electron Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the

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examiner should be directed to Examiner Courtney Brown, whose telephone number is 571-270-3284. The examiner can normally be reached on Monday-Friday from 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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